IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

BAUSCH HEALTH IRELAND LIMITED and SALIX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:22-cv-00020 (Kleeh)

DEFENDANT MYLAN PHARMACEUTICALS INC.'S OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

The Parties dispute the meaning of two claim terms. The two separate disputes reflect a common theme: Defendant Mylan Pharmaceuticals Inc. ("MPI") proposes the Court apply the ordinary and customary meaning of both terms, whereas Plaintiffs Bausch Health Ireland Limited ("Bausch") and Salix Pharmaceuticals, Inc. ("Salix") are dissatisfied with the way the patentee drafted the claims and now ask the Court to re-write the claims to suit their litigation goals.

The meaning of the claim term "storage" is disputed. That term has a well-understood meaning that is used consistently and unambiguously throughout the relevant patent specification and prosecution histories. Yet, Plaintiffs ask the Court to interpret "storage" to include unstated temperature and humidity conditions. Plaintiffs' request, which would "read-in" or "import" additional, specific requirements to the claim language, is inconsistent with the intrinsic evidence and Federal Circuit law.

The meaning of the claim terms "alpha-Asp-9-plecanatide (RRT 1.33)" and "iso-Asp2-plecanatide (RRT 0.96-0.97)" is also disputed. The disputed issue is the meaning of the claim language "RRT 1.33" and "RRT 0.96-97." "RRT" refers to "relative retention time," which is a metric used in a form of testing called chromatography. "RRT" is a well-known metric discussed in the intrinsic record and used consistently and unambiguously throughout the relevant patent specifications and prosecution histories. Yet, Plaintiffs ask the Court to delete "RRT 1.33" and "RRT 0.96-97" from the claims. Plaintiffs' request, which would "read-out" specific requirements from the claim language, is inconsistent with the intrinsic evidence and Federal Circuit law.

Plaintiffs' dissatisfaction with the claim language as written appears to stem from the fact none of the inventions originated from Plaintiffs. Rather, Plaintiffs purchased the inventions from a bankruptcy sale in 2019. Thus, the die for the claim language at issue was cast before Plaintiffs'

purchase, and Plaintiffs now ask the Court to make improper changes to express claim language that is, as written, readily understandable and unambiguous. Accordingly, MPI's proposal to adopt the ordinary and customary meaning of each of the two disputed terms should be granted, and Plaintiffs' proposals should be denied.

II. BACKGROUND

Two patent families are at issue for claim construction. One patent family shares a common specification and generally relates to pharmaceutical formulations containing plecanatide and methods of treating chronic constipation via oral administration of those formulations (the "formulation/method patents").[1] The other family shares a different common specification and generally relates to purified plecanatide and the methods of making it (the "purified plecanatide patents").[2]

With respect to both patent families, non-party Synergy Pharmaceuticals, Inc. ("Synergy") originally filed the patent applications (in the 2010-2013 timeframe) and prosecuted the patents. Synergy also filed the NDA for Trulance®, which received FDA approval in 2017. On December 12, 2018, Synergy filed a voluntary bankruptcy petition in the United States Bankruptcy Court for the Southern District of New York. *See* Docket No. 18-14010. Bausch then purchased the rights to Trulance® and the patents-in-suit after Synergy's bankruptcy. Ex.[3] 1.

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[1] U.S. Patent Nos. 9,616,097 ("'097 patent"); 9,610,321 ("'321 patent"); 9,919,024 ("'024 patent"), and 9,925,231 ("'231 patent"). Citations in this brief to common specification will be to the '097 patent unless otherwise noted.

[2] U.S. Patent Nos. 10,011,637 ("'637 patent"); 11,142,549 ("'549 patent"); and 11,319,346 ("'346 patent"). Citations in this brief to common specification will be to the '637 patent unless otherwise noted.

[3] "Ex." refers to exhibits attached hereto.

All four "formulation/method" patents issued to Synergy between 2017 and 2018. D.I. 91-2 at (45), (73); D.I. 91-3 at (45), (73); D.I. 91-4 at (45), (73); D.I. 91-5 at (45), (73). One of the three "purified plecanatide" patents (the '637 patent) issued to Synergy in 2018. D.I. 91-6 at (45), (73). The other two (the '549 and '346 patents) issued to Bausch (as the successor in interest to Synergy) in 2021 and 2022.[4] Ex. 2 at (45), (73); Ex. 3 (45), (73).

III. LEGAL STANDARDS

Claim terms have their "ordinary and customary meaning" to "one of skill in the art when read in the context of the specification and prosecution history"—i.e., the intrinsic record. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc); *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (citing *Phillips*, 415 F.3d at 1313). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution." *Hill-Rom Servs.*, 755 F.3d at 1371 (quoting *Thorner v. Sony Comput. Entm't Am. LLC,* 669 F.3d 1362, 1365 (Fed. Cir. 2012)). "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term." *Id.* (internal quotations & citation omitted). The Federal Circuit has "repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005) (citing *Bell Atl. Network Servs. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001); *see also Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d 1302,

[4] Because Plaintiffs did not prosecute most of the patents, this brief generally refers to Synergy and its agents as the "patentees."

1307 (Fed. Cir. 2000) ("Absent an express intent to impart a novel meaning, claim terms take on their ordinary meaning"). Disavowal of a claim term's plain and ordinary meaning requires "a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs.*, 755 F.3d at 1372 (internal quotations & citation omitted). Neither exception applies to the disputes presently before the Court. As discussed in detail below, both disputed terms should be understood in accordance with their ordinary and customary meaning.

A person of ordinary skill in the art's ("POSA's") understanding of the claim term, in the context of the entire patent, "provides an objective baseline from which to begin claim interpretation." *Phillips*, 415 F.3d at 1313. Where this understanding is not immediately apparent, courts may look to other sources, such as the prosecution history and extrinsic evidence. *Id.* at 1317. A court may rely on extrinsic evidence, including expert testimony and learned treatises, to determine a claim term's plain meaning, although extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Id.* (citation omitted). Expert testimony can be useful to provide background on the technology, to explain how an invention works, and to establish that a term has a particular meaning in the pertinent field. *Id.* at 1318.

IV. CLAIM TERMS IN DISPUTE

A. "Storage"

Claims	Term	Plaintiffs' Position	MPI's Position
'231 patent, all asserted claims; '024 patent, all asserted claims; '097 patent, all asserted claims; and '321 patent, all asserted claims	"storage"	"stored under normal conditions of room temperature (25° C.) and 60% relative humidity"	"storage under any conditions"

Claim 1 of the '097 patent is shown below with the disputed term "storage" in bold:

> 1. An oral dosage formulation of a Guanylate Cyclase-C (GCC) agonist peptide consisting of
>
> a per unit dose of 3.0 mg or 6.0 mg of a peptide consisting of SEQ ID NO:1,
>
> wherein said peptide is a (4,12; 7,15) bicycle,
>
> an inert low moisture carrier and a lubricant,
>
> wherein the peptide has a chromatographic purity of no less than 91% after **storage** for at least three months.

D.I. 91-3 (emphasis added).

The claim language "wherein the peptide has a chromatographic purity of no less than 91% after **storage** for at least three months" appears in every claim of the '097, '231, '024, and '321 patents. On its face, that claim language establishes a specific lower boundary for purity of the peptide (91%) *after* a period of three months during which the claimed peptide is stored. The claim language does not require any specific form of storage or conditions related to storage beyond the three-month duration of the storage.

1. "Storage" Has Its Ordinary and Customary Meaning

The term "storage" is not defined in the specification or prosecution history. It has an ordinary and customary meaning in the context of pharmaceutical dosage forms, which is consistent with the everyday use of the term. Put simply, "storage" describes placing a dosage form for safekeeping such that the dosage form can be retrieved later. Buckton Decl.[5], ¶ 32. There are many ways to store a dosage form. For example, placing a bottle of pills placed in a medicine cabinet is one form of storage. Placing pills into a pill box and then placing the pill box into a refrigerator is another form of storage. There is a large variety of packaging methods, temperature conditions, humidity conditions, and other conditions that can be considered "storage" (e.g., in a bottle, with or without a desiccant, in a blister package, etc.). For example, the United States Pharmacopiea ("USP"), a well-known and often-used reference, defines "storage conditions" to include (among other things) "Refrigerator," "Cold," "Cool," "Room Temperature," and "Dry Place.," each includes different temperature, humidity, or other conditions as appropriate for storage of a specific product. Ex. 4 at 272; Buckton Decl., ¶ 35. If a dosage form must be stored under specific conditions for any reason, those required conditions are expressly provided or stated. Buckton Decl., ¶¶ 34-38, 40.

The intrinsic evidence confirms that specific storage conditions are expressly provided or stated. For example, claim 5 of the '097 patent (which depends on independent claim 1) includes specific temperature and humidity conditions:

> 5. The oral dosage formulation of claim 1, wherein the GCC agonist peptide is stabilized against degradation for a period of at least 18 months **at 30° C. and 65% relative humidity,** or at least 18 months **at 25° C. and 60% relative humidity**, or at least 18 months **at 2-8° C**.

D.I. 91-3 (emphasis added).

[5] "Buckton Decl." refers to the Declaration of Dr. Graham Buckton, filed herewith.

Claim 5 of the '231 patent also includes expressly stated specific temperature and humidity conditions. D.I. 91-5 ("The oral dosage formulation of claim 1, wherein the GCC agonist peptide is stabilized against degradation for a period of at least 18 months **at 30 ° C. and 65% relative humidity,** or at least 18 months **at 25 ° C. and 60% relative humidity**, or at least 18 months **at 2-8 ° C.**" (emphasis added)). As illustrated by claim 5 of the '097 patent and claim 5 of the '231 patent, to the extent specific temperature or humidity conditions are required by a claim, the claims expressly include them. The absence of similar language in independent claim 1 of the '097 patent (or any other independent claims of the '097, '231, '024, or '321 patent) provides conclusive evidence that the scope of those claims is not restricted to any specific storage conditions, including temperature or humidity conditions.

The specification confirms the term "storage," as used in the claims, does not imply any specific temperature or humidity conditions. The specification consistently uses "storage" in its ordinary sense—i.e., placing a dosage form for safekeeping such that the dosage form can be retrieved later. For example, the specification states that the claimed invention "provides stability against degradation both during the manufacturing process and **storage** of the formulation." D.I. 91-3 at 7:38-40. *See also id* at 7:45-47 ("Plecanatide is a hygroscopic peptide requiring the control of water during manufacture and **storage** to promote long term stability.") (emphasis added), 7:61-65 ("The invention further includes scavengers of residual formaldehyde . . ., and discloses packaging confirmations to minimize oxygen exposure and water vapor during **storage**.").

According to the specification, the term "stability" "refers to the resistance of the peptide to chemical or physical degradation over time." *Id.* at 8:50-52. The specification states "[p]referably, a stable formulation of the invention retains an amount of the peptide in the formulation over a period of time that is at least 90%, preferably at least 95%, and most preferably at least 99% the amount of

peptide initially present in the formulation." *Id.* at 8:52-57. Stability is important because the peptide degrades too much upon storage, then an insufficient amount of peptide will remain, and the dosage form will lack potency.

The specification describes a variety of ways to store the claimed dosage form, including a blister pack made of a material that is impermeable to water vapor and oxygen—e.g., a metal foil, which is optionally flushed with an inert gas (i.e., no water or oxygen). *Id.* at 4:53-5:2. Other examples include storage in a bottle (or vial) with a seal and optionally a desiccant. *Id.*[6] Other examples in the specification discuss a variety of different "storage" conditions, including at multiple different temperatures and relative humidities, and with an open or closed vial. *Id.* at 82:56-83:30 (Example 4) ("[g]lass vials were stored at 40 C/75 RH open or closed" over 1-3months), 84:49-85:7 (Example 8) ("1 month storage at the indicated temperature"; storage at 2-8 C and 25 C/60RH.).[7] One such example, Example 20, specifically describes testing using "Storage Conditions" of 40°C/75RH%[8], 30°C /75RH%, 25°C/65%RH and 5°C. over 1-10 months. *Id.* at 94:56-109:44.

The specification teaches that in certain embodiments the formulation is "stable" in a variety of different storage conditions, including:[9]

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[6] Claim 7 of the '097 patent also is directed to the formulation of claim 1, limited to a tablet or capsule, wherein the capsule or tablet is in a blister pack or strip. *See* D.I. 91-3.

[7] Open or closed vial can simulate whether the consumer packaging is or is not moisture-tight.

[8] "RH%" means percent relative humidity.

[9] *See, e.g.*, *id.* at 8:62-9:10 ("In one embodiment, the peptide is chemically stable in the formulation for a period of time that is at least 18 months, at least 20 months, or at least 24 months when **stored at 25 degrees Celsius (25 C) and 60% relative humidity**. In one embodiment, the peptide is chemically stable in the formulation for a period of time that is at least 18 months, at least 20 months, or at least 24 months **when stored at 2-8 degrees Celsius (2-8 C)**. In one embodiment, the peptide is chemically stable in the formulation for a period of time that is at least 3 months, 12

- at least 18 months, at least 20 months, or at 65 least 24 months **when stored at** 25 degrees Celsius (25 C) and 60% relative humidity.
- at least 18 months, at least 20 months, or at least 24 months **when stored at** 2-8 degrees Celsius (2-8 C).
- at least 3 months, 12 months, 18 months and preferably 24 months **when stored at** 25 degrees Celsius (25 C) and 60% relative humidity.

Thus, the specification discusses a large variety of storage methods and conditions without limiting the term "storage" to any specific temperature or humidity. When a specific storage condition is required, the claims and specification expressly state the required conditions. *See Arthrodesis Tech. LLC v. Wright Med. Tech.*, No. 21-11 (MN), 2022 WL 3700901, at *6 (D. Del. Aug. 26, 2022) (declining to include "talus" in a construction because "the patentee knew how to say that" based on the specification but did not use the word in the claims).

2. The Court Should Reject Plaintiffs' Inappropriate Attempt to Import Additional Limitations into the Claim

Plaintiffs ask the Court to re-write the claims by interpreting "storage" to include multiple very specific conditions: (1) "normal conditions," (2) "room temperature (25°C.)," and (3) "60% relative humidity." Plaintiffs' proposal is derived from just one of the many examples of temperature and humidity conditions disclosed in the specification. That proposal should be rejected because re-writing claim language to mimic the description of one or more specific examples found in the specification has been described as "one of the cardinal sins of patent law." *Blazer v. Best Bee*

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months, 18 months and preferably 24 months **when stored at 25 degrees Celsius (25 C) and 60% relative humidity**. In one embodiment, the peptide is chemically stable in the formulation for a period of time that is at least 3 months, 18 months and preferably 24 months **when stored at 30 degrees Celsius (30 C)**." (emphasis added)); *see also id.* at 6:7-12 ("Preferably, the GCC agonist peptide as made is stabilized against chemical or physical degradation for a period of at least 18 months at **30° C. and 65% relative humidity**, or at least 18 months at **25° C. and 60% relative humidity**, or at least **18 months at 2-8° C**." (emphasis added)).

Bros. LLC, No. 22-1033, 2022 U.S. App. LEXIS 31589, at *12 (Fed. Cir. Nov. 16, 2022) (citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001)); s*ee also Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988) ("Where a specification does not require a limitation, that limitation should not be read from the specification into the claims." (emphasis omitted)); *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333–34 (Fed. Cir. 2007) (Adding limitations from the specification is impermissible "absent a clear disclosure that the patentee intended the claims to be limited as shown." (citing *Phillips*, 415 F.3d at 1323)).

"[I]t is important not to import into a claim limitations that are not a part of the claim." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). For example, the Federal Circuit in *Blazer v. Best Bee Brothers,* recently overruled a district court's construction that "erroneously import[ed] limitations into [the term] 'receptacle adapter' based on particular embodiments described in the specification." 2022 U.S. App. LEXIS 31589 at *11-13. "The district court, in confining the scope of 'receptacle adapter' to three particular embodiments, crossed [the] important line" against reading-in limitations from the specification. *Id.* at *12. Similar to this case, dependent claims were key to the court's analysis, in which it explained because "[c]ertain dependent claims recite specific 'receptacle adapter' embodiments . . . [t]he phrase 'receptacle adapter,' then, must encompass not only the three specific types of adapters identified by the district court but also holes and other structures with the property common to the full range of specification embodiments." *Id.*

Here, the same holding should apply, and Plaintiffs' request should be denied. There is no basis to import limitations from certain examples found in the specification, especially where the claims themselves show conclusively that when the patentees intended to claim specific temperature

and humidity conditions, they did so expressly. *SuperGuide*, 358 F.3d at 875 ("The written description, however, is not a substitute for, nor can it be used to re-write, the chosen claim language."). Plaintiffs' proposed construction is also improper because it is unclear what Plaintiffs intend "normal conditions" to encompass (if anything) beyond temperature and humidity. The term "normal conditions" is not used in the specification or prosecution history. Moreover, there are no default "normal conditions" in the pharmaceutical arts. *See* Buckton Decl., ¶¶ 34-37, 40.

Similarly, with respect to "room temperature," the specification does not use or define that term. Plaintiffs seek to unilaterally define it to mean 25°C and 60% relative humidity, but that definition is irreconcilable with the ordinary meaning of the term. Buckton Decl., ¶¶ 41, 50. The USP, for example, defines "room temperature" as the "[t]he temperature prevailing in a working area" (Ex. 4 at 272) and acknowledges that "'room temperature' is used in different ways in different countries…" Ex. 5 at 2700. The USP divides the world into four different climate zones, each with very different mean temperatures (~21-30°C) and percent relative humidity (35-70%). *Id.* at 2700-2701. The USP approach is consistent with real world experience, which tells us that room temperature and/or humidity implicates a wide range of potential conditions.

Thus, the Court should reject Plaintiffs' proposed construction of "storage" as inconsistent with both intrinsic and extrinsic evidence as well as applicable Federal Circuit law. *SuperGuide*, 358 F.3d at 875 ("[A] particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." (citing *Electro Med. Sys. S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994)).

B. Purified Plecanatide Patents

1. alpha-Asp-9-plecanatide (RRT 1.33) and iso-Asp2-plecanatide (RRT 0.96-0.97) Should Be Given Their Plain and Ordinary Meaning

Claim	Term	Plaintiffs' Position	MPI's Position
'637 patent, claims 1-13	"alpha-Asp-9-plecanatide (RRT 1.33)"	"the compound alpha-Asp-9-plecanatide"	"alpha-Asp-9-plecanatide having a relative retention time of 1.33"
'637 patent, claim 13	"iso-Asp2-plecanatide (RRT 0.96-0.97)"	"the compound iso-Asp2-plecanatide"	"iso-Asp2-plecanatide having a relative retention time of 0.96-0.97"

Claim 1 of the '637 patent is shown below with the disputed term "alpha-Asp-9-plecanatide (RRT 1.33)" in bold:

> 1. A purified peptide comprising the GCC agonist amino acid sequence of SEQ ID NO: 1, wherein the purified peptide has the following characteristics:
> a) has a bulk density of not greater than 0.1 g/mL;
> b) contains less than 50 ppm acetamide;
> c) less than 0.25% **alpha-Asp-9-plecanatide (RRT 1.33)** per total weight of peptide; and
> d) less than 0.05% trifluoroacetic acid (TFA) per total weight of peptide.

D.I. 91-6 (emphasis added).

Claims 2–13 depend from claim 1, thus claims 1–13 of the '637 patent claim a purified peptide that "has the following characteristics: . . . less than 0.25% **alpha-Asp-9-plecanatide (RRT 1.33)** per total weight of peptide . . . ." *Id.* (emphasis added). That claim language establishes an upper boundary for the amount of alpha-Asp-9-plecanatide (RRT 1.33) that can be present in the claimed purified peptide. The claim language specifically identifies alpha-Asp-9 plecanatide with an RRT of 1.33.

Claim 13 of the '637 (which depends from claim 1) includes the following language:

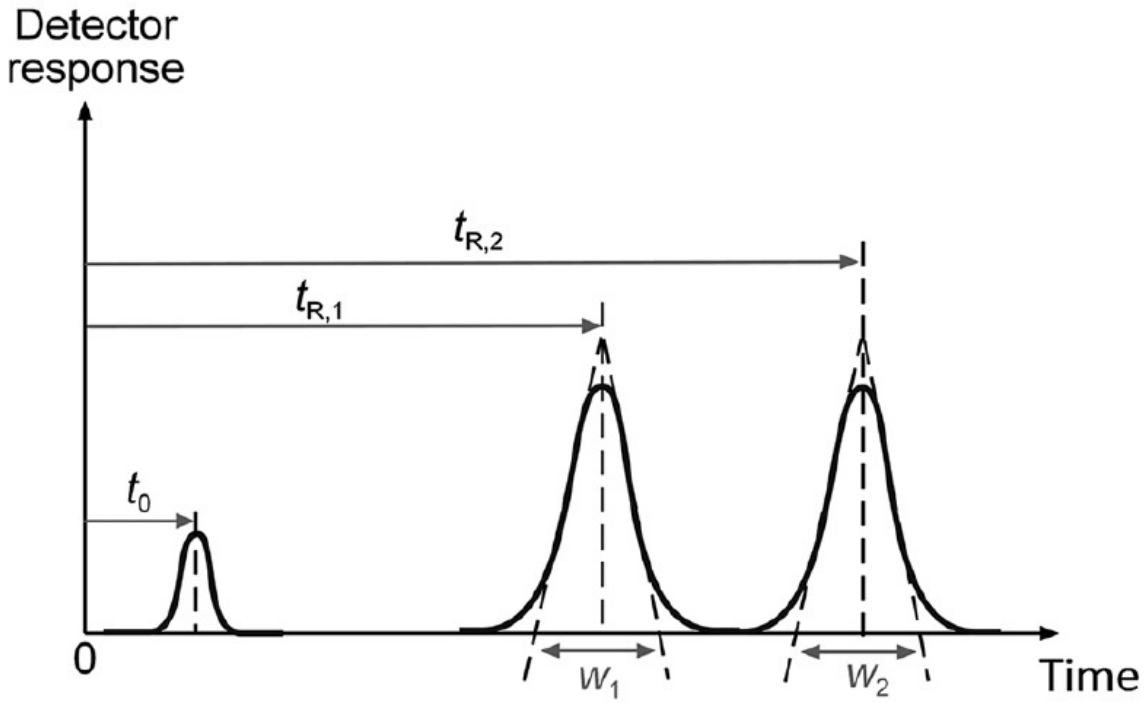
> 13. The purified peptide of claim 1, wherein the peptide **further contains iso-Asp2-plecanatide (RRT 0.96-0.97)** at less than 2% of the total weight of the peptide."

Id. (emphasis added). Thus, the language of claim 13 states an additional requirement that the claimed peptide have less than a prescribed amount of "**iso-Asp2-plecanatide (RRT 0.96-0.97)**." *Id.* (emphasis added).

The dispute presented by this term boils down to whether the claim language "RRT 1.33" and "RRT 0.96-0.97" has meaning or, as Plaintiffs have proposed, are superfluous words that the Court should delete from the face of the claims. The intrinsic record—indeed the claim language itself—supports MPI's position that "RRT 1.33" and "RRT 0.96-0.97" must have meaning. The mere appearance of those words in the claim language compels the common sense conclusion that words in a claim must have meaning. *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1257 (Fed. Cir. 2010) (quoting *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("Claims must be 'interpreted with an eye toward giving effect to all terms in the claim.'"); *see also Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008); *Elekta*, 214 F.3d at 1307-08. The claim language "alpha-Asp-9-plecanatide (RRT 1.33)" unambiguously refers to alpha-Asp-9-plecanatide having an RRT of 1.33. Similarly, in the claim language "iso-Asp2-plecanatide (RRT 0.96-97)" unambiguously refers to iso-Asp2-plecanatide having an RRT of 0.96-97.

RRT stands for "relative retention time", which the patent acknowledges is a term used in chromatography. D.I. 91-6 at 3:45-48. Chromatography is a technique used to separate a mixture of components into isolated individual components. "Retention time" is the time elapsed between 1) introduction of a mixture into the chromatographic system; and 2) the time at which the individual component of interest is detected by the chromatographic system. By way of example, in the figure below, $t_{R,1}$ and $t_{R,2}$ represent the retention times of two different components. A retention time is *relative* when it is presented as a ratio between the retention times of two different components. Ex.

6 at 14. The ratio is obtained by dividing one retention time by the other, such as $t_{R,2}$ by $_{tR,1}$ in the figure below.



Ex. 7 at 2 (Fig. 1.1).

The specification uses the term "RRT" consistent with the ordinary and customary meaning of the term. The specification specifically describes "alpha-Asp-9-plecanatide (RRT 1.33)": "For example, the purified peptide contains less than 0.15% alpha-Asp-9-plecanatide (which has a Relative Retention Time (RRT) of ~1.33 from the ultra-performance liquid chromatography (UPLC) analysis described herein)." D.I. 91-6 at 7:44-46, 3:45-48. The specification also describes "iso-Asp2-plecanatide (RRT 0.96-97)": "For example, the purified peptide is substantially free of iso-Asp2-plecanatide (RRT 0.96-0.97) ….". *Id.* at 4:13-15.

Thus, the intrinsic record and Federal Circuit authority support MPI's proposal that the claim language "RRT 1.33" and "RRT 0.96-97" should be given their ordinary and customary meaning.

2. The Court Should Not Read Out Express Limitations from the Claims

On the other hand, Plaintiffs ask the Court to edit the claims to delete "RRT 1.33" and "RRT 0.96-97." In other words, Plaintiffs propose to remove an express limitation from the claims. Plaintiffs' request is inconsistent with Federal Circuit law. *Merck & Co*, 395 F.3d at 1372; *see also Elekta*, 214 F.3d at 1307-08 (construing claim to avoid rendering the 30 degree claim limitation superfluous as "the unambiguous language of the amended claim controls over any contradictory language in the written description"); *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 769-70 (Fed. Cir. 1996) (Where "the claim language itself distinguishes between the openings that are adjacent to the side walls and those that are adjacent to the end walls," the court rejected the district court's claim construction, which "obliterated that distinction," as it "was inconsistent with the specification and drawings and rendered superfluous the claim requirement for openings adjacent to the end walls."); *Inline Connection Corp. v. AOL Time Warner, Inc.,* 347 F. Supp. 2d 56, 72 (D. Del. 2004) ("Defining 'high' as simply meaning that the 'frequency band' is 'above' the voice band, as Inline suggests, would make the words 'high frequency band' superfluous since the entire phrase in question already requires the 'high frequency band' to be limited to those 'frequencies above the highest frequency of the telephone voice band.'"). No legitimate reason exists here to depart from that rule. Thus, the Court should give meaning to these terms. *See Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1374 (Fed. Cir. 2015) ("[T]o construe this term to not require that playback starts at the time the caller is placed on hold, as Info-Hold asks us to do, would be to read the word 'placed' out of the claims of the patent. Our precedent prohibits us from adopting such a construction.").

Finally, the face of the claims illustrates that the patentees intentionally and expressly included specific RRTs in these claims. If the Court were to delete language from the claims, then the public would be left to guess at which of the remaining claim language is similarly superfluous.

As the Federal Circuit has explained, "[a]llowing a patentee to argue that physical structures and characteristics specifically described in a claim are merely superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is merely superfluous, nonlimiting elaboration. For that reason, claims are interpreted with an eye toward giving effect to all terms in the claim." *Bicon*, 441 F.3d at 950. *See also Info-Hold,* 783 F.3d at 1374; *Becton*, 616 F.3d at 1257; *Cat Tech*, 528 F.3d at 885; *Elekta*, 214 F.3d at 1305-07. Accordingly, the Court should give the RRT terms their ordinary and customary meaning.

V. CONCLUSION

For the foregoing reasons, MPI respectfully request the Court to adopt MPI's proposed constructions.

Respectfully submitted this 12the day of January, 2023.

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CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of January 2022 I electronically filed a copy of the foregoing **"Defendant Mylan Pharmaceuticals Inc.'s Opening Claim Construction Brief"** with the Clerk of the Court using the CM/ECF system, which will send notice thereof to the following counsel of record:

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